

**REMARKS**

This is in response to the 23 December 2008 office action.

Withdrawn claims 1-22 remain canceled without prejudice or disclaimer of the subject matter therein. Applicant reserves the right to file a continuing application including the subject matter of the canceled claims.

**The 35 U.S.C. 112, first paragraph, rejection.**

Claim 29 stands rejected under 35 U.S.C. 112, first paragraph. The office action states

[c]laim 29 recites the limitation ‘the hollow cap **encapsulates substantially all** of the bone instrumentation which projects from the bone.’ There is no disclosure or inherency as originally filed that the hollow cap encapsulates substantially all of the bone instrumentation which projects from the bone. (Office action at page 2.)

The office action at page 3 finds applicant’s remarks regarding this rejection to be not persuasive because “all that is supported in the specification as originally filed is that the cap/casing can be placed over certain projecting parts, not substantially all of the projecting parts and not necessarily substantially all of any given part.”

Applicant’s remarks on the 35 U.S.C. 112, first paragraph, rejection in our 04 September 2008 amendment are incorporated herein by reference. See especially pages 5-8 of our 04 September 2008 amendment. As per our earlier remarks, the test of whether the disclosure enables the language of the claim is whether one reasonably skilled in the art can make or use the invention from the disclosure in the patent application with information known in the art and without undue experimentation.<sup>1</sup> The present specification at, for example, paragraph 0004 (of the published version, 2005/0049596) states that the cap is dimensioned to “encapsulate projecting parts of instrumentation installed in the bone.” Paragraph 0017 describes “[t]he shield or cover... closely fits onto the instrumentation” and “[t]he shield or cover prevents ingrowth of bone or fibrous tissue into interstices of the instrumentation because it provides a mechanical barrier to such intrusion.” One of ordinary skill in the art would have understood the variety of covers available to accomplish the close fit mechanical barrier disclosed in the specification. The office action does not provide any reasons or explanation why one of ordinary

---

<sup>1</sup> See U.S. v. Teletronics Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed Cir. 1988).

skill in the art being aware of the above disclosure would not have been aware of a hollow cap that **encapsulates substantially all** of the bone instrumentation as recited in claim 29. The office action omits this important explanation. For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

**The 35 U.S.C. 112, second paragraph, rejection.**

Claims 26-28 and 34 stand rejected under 35 U.S.C. 112, second paragraph. The terminology “a second suture string” in claim 26 is asserted to be not appreciably different from the “plurality of first suture strings” as recited in claim 25. It is urged that it is unclear whether the second and first suture strings have the same properties. Claim 34 is rejected but there is no detailed explanation and claim 34 does not include recitation of first and second suture strings and does not appear to be properly rejected on the same basis as claims 26-28.

Applicant’s remarks on the 35 U.S.C. 112, second paragraph, rejection in our 04 September 2008 amendment are incorporated herein by reference. As per our earlier remarks, a decision as to claim indefiniteness requires a determination of whether those skilled in the art would understand what is claimed.<sup>2</sup> Claim 25 recites first ends of the first suture strings connected to the hollow cap and the second ends of the first suture strings are threaded through the cinch ring for tightening the hollow cap to the cinch ring. The first suture strings are supported in the disclosure at, for example, paragraph 0022 which discloses suture strings 46a that are tied to the lower edge of the cap 40 and that are threaded through openings 42a in cinch ring 42. Claim 26 adds “a second suture string with a first end of the second suture string coupled to an edge of the cap and with a second end of the second suture string coupled to the cinch ring.” The second suture strings are supported in the disclosure at, for example, paragraph 0022 which discloses suture two strings 46b on opposite sides of the cap having an end tied to the cinch ring to “tie the cinch ring to the cap” so that the cinch ring does not slip away from the cap during handling. One of ordinary skill in the art would understand the difference between the claimed first and second suture strings as recited in claims 26-28 and 34. It is believed that the rejection intends the indefiniteness to apply to claim 33 instead of claim 34 because claim 33 adds an additional suture string and claim 34 does not. Claim 33 adds a non-adjustable suture string to the adjustable suture string of claim 32. Claim 33 is definite for the same reasons as

---

<sup>2</sup> See Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

discussed above with respect to claims 25 and 26. For at least these reasons applicant requests reconsideration and withdrawal of this ground of rejection.

**The 35 U.S.C. 102(b) rejection over Ellman.**

Claims 23-34, 36, 38 and 39 stand rejected under 35 U.S.C. 102(b) as anticipated by Ellman (U.S. Patent No. 4,428,375).

To support a rejection of a claim under 35 U.S.C. 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference.<sup>3</sup>

Ellman discloses a bag 15 to compress an organ to assist in healing a fracture in the organ. Ellman discloses "bag 15 has a mesh or network construction" (column 2, line 32). The mesh has openings 19. Ellman states that "another advantage is that the multiple interstices or openings in the net allows ingrowth of tissue through the net openings and around the net solid parts and thus enhances healing." (Column 3, lines 55-58.)

Applicant's claims have been amended to clarify that the cover or shield separates the bone implant from substantially all of the surrounding soft tissue. As discussed above, the disclosure supports this clarification. Ellman's bag 15 does not and cannot separate the implant from the soft tissue because the bag 15 has holes in the bag 15 (i.e., a mesh has holes or openings which as disclosed in Ellman permit ingrowth). Accordingly Ellman does not anticipate the claimed invention and Ellman actually teaches away from the claimed invention in that Ellman discloses the desirability of ingrowth (as quoted above) whereas applicant's claimed invention prevents ingrowth. One following the teaching of Ellman would be discouraged from following the path set out by applicant and would be led in a direction away from the invention provided by the applicant.

At page 5 of the office action it is urged that our arguments regarding Ellman are not persuasive because "[a] barrier is a rather broad term, as the mesh network clearly would prevent any soft tissue larger than an opening from passing through as clearly depicted in Figures 3 and 4." Ellman discloses that the mesh or network of the bag 15 has holes 19 which are "3-9 mm in size" (column 2, lines 46-52). Even a layman would know that Ellman's bag 15 with holes that

---

<sup>3</sup> See *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

size does not and can not prevent “ingrowth of substantially all of the surrounding soft tissue through the cap into the bone instrumentation which projects from the bone” as recited in claim 23, is not “adapted to separate the part of the pedicle screw from surrounding bone and soft tissue...” as recited in claim 30 and is not a “means for separating a projecting portion of bone instrumentation which has been installed in bone in vivo from substantially all of the surrounding soft tissue and for providing a medically safe physical barrier between the part of the bone instrumentation which projects from the bone and the surrounding soft tissue so that the cap prevents ingrowth of substantially all of the surrounding soft tissue into the bone instrumentation which projects from the bone” as recited in claim 36. For at least the above-noted reasons, Ellman does not anticipate the invention of independent claims 23, 30 and 36 (and dependent claims 24-29, 31-34, 38 and 39).

**The 35 U.S.C. 102(b) rejection over Harms et al.**

Claims 40 and 41 are rejected as anticipated by Harms (U.S. Patent No. 4,820,305).

Harms et al. discloses a screen member 1 that is a place holder for a vertebra body. A pedicle screw is shown in Fig. 4 with the pedicle screw being fixed to the screen member 1. Harms et al. screen member 1 does not and cannot separate the implant from the soft tissue because the screen member 1 has holes that like Ellman is not “a barrier material snugly covering only the portion of the bone implant which projects from the bone” as recited in claim 40. The screen member 1 in Harms et al. is not barrier material which “prevents ingrowth of substantially all of the surrounding tissue into the instrumentation” as recited in claim 40.

For at least the above-noted reasons, Harms et al. does not anticipate the invention of independent claim 40 and dependent claim 41.

**New Claims.**

New dependent claims 42-44 have been added. Claim 42 is dependent on claim 40 and adds that the barrier material is designed to be adjusted around the portion of the bone implant which projects from the bone so that it snugly covers the portion of the bone implant which projects from the bone. The screen 1 in harms is not adjustable to snugly cover as recited in claim 42. Claims 43-44 add that the barrier material is hydrogel. None of the relied on prior art teach or suggest hydrogel as recited in dependent claims 43-44.

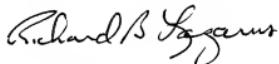
**Conclusion.**

For all of the above reasons claims 23-44 appear to be in condition for allowance and such is respectfully requested.

If there is any issue remaining to be resolved, the examiner is invited to telephone the undersigned so that resolution can be promptly effected.

It is requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees, being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg, Deposit Account No. 02-1010 (6714-46501).

Respectfully submitted,  
BARNES & THORNBURG LLP



Richard B. Lazarus  
Reg. No. 48,215  
Tel. No. (202) 371-6348